

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the following remarks.

### **I. CLAIM STATUS**

Claims 1, 5, 7, and 9-10 were pending in this application when last examined.

Claims 2, 4, 6, and 8 stood cancelled without prejudice or disclaimer thereto.

Claims 1, 5, 7, and 9-10 were examined on the merits and stand rejected.

### **II. ADVISORY ACTION**

In the Advisory Action issued July 28, 2011, the Examiner referred to the description in col. 15, lines 5-10 of Kittleman et al. Specifically, the Examiner alleged that “Mg<sup>2+</sup> is used to precipitate the contaminant pyrophosphatase in the form of magnesium pyrophosphatase”. The Examiner also referred to USPN 5,922,577 (‘577 patent), and alleged that “(‘577 patent) also teaches the use of divalent cation can remove Pi or PPi from various processes in glycosyl transferase cycles by precipitation”.

However, Applicants respectfully submit that the Examiner’s allegations appear to be invalid. Both Kittleman et al. and ‘577 patent only disclose using divalent cation *in the catalytic reaction of CTP and NeuAc*. In fact, in ‘577 patent, divalent cation can only be used in “various processes in glycosyl transferase cycles” as mentioned by the Examiner. In col. 15, lines 5-10 of Kittleman et al., it is disclosed that Mg<sup>2+</sup> is used “in the course of the reaction” of CTP and NeuAc (see line 5).

In both references, divalent cation is added to accelerate the catalytic reaction, or used to remove byproduct (pyrophosphate) which inhibits the catalytic reaction. Hence the references *only* teach role(s) of the divalent cation *in the course of the catalytic reaction*. None of these references teaches or suggests the use of the divalent ion in a process for purification of CMP-NeuAc obtained by catalytic reaction as claimed.

In Example 6 of Kittleman et al., including col. 15, lines 5-10, the CMP-NeuAc produced is purified with HPLC column to yield 45-96% purity (see col. 15, lines 15-18, and Table 3). Please note that Kittleman et al. does not teach or suggest using divalent ion for purification of produced CMP-NeuAc, even though they used the divalent ion during the catalytic reaction to remove pyrophosphatase. *These descriptions thus rather suggest that divalent cation is not*

*useful in the purification of CMP-NeuAc*, and the skilled person reading Kittleman et al. would not be motivated to use divalent cation in a process for purification of CMP-NeuAc obtained by the catalytic reaction.

Precipitation of Pi or PPi with divalent cation may itself be a known reaction in the art, however, even so, it is not the only feature of the claimed process. The claimed process comprising the steps (1) to (4) which are performed in the specific sequence, thereby the claimed process provides CMP-NeuAc of quite high purity without conducting HPLC treatment. The purity level achieved in the claimed process is comparable to HPLC purification as disclosed in Kittleman et al. None of the references teaches or suggests the steps (1) to (4) performed in the specific sequence as claimed. Also they do not teach or suggest the purification process of CMP-NeuAc without including HPLC treatment as claimed. Hence the claimed process would not be obvious to the skilled person and the purity of CMP-NeuAc achieved in the claimed process is unexpectedly high.

For at least the above reasons, Applicants respectfully assert that a person having ordinary skill in the art would find no reason in the teachings of the cited references to modify or combine their teachings in order to arrive at the claimed invention, nor would he have any reasonable expectation of success in doing so. Therefore, Applicants respectfully assert that the rejection is untenable as applied to the claims and should be withdrawn.

**CONCLUSION**

In view of the foregoing remarks, it is respectfully asserted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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